


MAHARASHTRA POLLUTION CONTROL BOARD

Tel: 24010437/24020781/24014701		Kalpataru Point, 2 nd - 4 th Fl.
Fax: 24024068 / 24023516		Opp. Cine Planet Cinema,
Website: http://mpcb.gov.in		Near Sion Circle, Sion (E)
E-mail: ast@mpcb.gov.in		Mumbai-400 022.

Orange/ SSI

Date: 22/12/2014.

Consent No. BO/AST/RO-KN/EIC No KN-6643-14/E/CC- 12251

Consent to Establish under Section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary) Rules 2008.

[To be referred as Water Act, Air Act and HW (M, H&TM) Rules respectively].

CONSENT is hereby granted to,

M/s. Orax Pharma Pvt. Ltd.,
Plot No. B-5, Phase-I, MIDC, Dombivali,
Dist. Thane

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Establish is granted for a period up to commissioning of the unit or Five years whichever is earlier.
2. The Consent is valid for the manufacture of -

Sr. No.	Products	Quantity
	Only by Formulation	
1	Clopidogrel, Tablets USP 75 mg	14400000 Tablets/A
2	Levocetirizine Di HCL Tablets 5 mg	
3	Diclofenac Sodium Tablets BP50 mg	
4	Meloxicam Tablets BP7.5 mg	
5	Moxifloxacin HCL	
6	Atenolol Tablets BP 100 mg	
7	Amlodipine & Atorvastation Tablets	
8	Amlodipine Besylate Tablets 10 mg	

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent-NIL.
- (ii) The daily quantity of sewage effluent-NIL
- (iii) **Trade Effluent: Treatment- NA**
- (iv) **Trade Effluent Disposal: NA**
- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards:

(1)	Suspended Solids	Not to exceed	100	mg/l.
(2)	BOD 3 days 27 Deg. C.	Not to exceed	100	mg/l.

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes : NA**

(viii) **Other conditions:** The industry should monitor effluent quality regularly from MoEF approved laboratory.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and Rules there under: The daily water consumption for the following categories is as under:

i	Domestic	CMD
ii	Industrial Processing	2.00	CMD
iii	Industrial Cooling / Boiler	CMD
iv	Agriculture/Gardening	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT:**

(i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards.

Control Equipment: 1] Scrubber of sufficient capacity should be provided to process reactor or any other sources of emissions to limit the gaseous emissions.

Conditions for D.G. Set: NA

Standards for Emissions of Air Pollutants:

1	SPM/TPM	Not to exceed	150	mg/Nm ³
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(ii) **The applicant shall observe the following fuel pattern:- NA**

(iii) **The applicant shall erect the chimney(s) of the following specifications:-**

Sr. No.	APCS attached to	APCS provided	Height in meters
1	Formulation section	Dust Collector

(iv) The applicant shall provide ports in the chimney/(s) and facilitates such as ladder, platform etc. For monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. And these shall be painted / displayed to facilitate identification.

(v) The industry shall take adequate measures for control for noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. And 10 p.m. And night time is reckoned between 10 p.m. And 6 p.m.

(vi) **Other Conditions:**

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality regularly from MoEF approved laboratory.

6. **CONDITIONS UNDER HW (M, H & TM) RULES, 2008: NIL**

7. Whenever due to any accident or release of gases or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emissions and ensure that the emissions do not cause any harm or nuisance in the surrounding. The industry should not restart the process without permission of the Board and other statutory organizations as require under the law.
8. **General conditions:**
- (i) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement by 30th September every year on available open plot area, no. of trees surviving as on 31st March of the year and no. of trees planted by September end.
 - (ii) The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant and operate the same in case of power failure to maintain compliance with the terms and conditions of the consent. In the absence of same, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.
 - (iii) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent/ emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.
 - (iv) The firm shall submit MPCB, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as pre the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992 before 30th September every year.
 - (v) The applicant shall install a separate meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained. The applicant shall also submit a comparative statement of designed power and chemical consumptions vis-a vis actual power and chemical consumption along with Environmental statement.
 - (vi) Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes/sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
 - (vii) The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
 - (viii) The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
 - (ix) The applicant shall maintain good house keeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
09. If CETP dose not work for achieving standards & problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.
10. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
11. The industry shall also comply with the Industry specific standards notified under Environment Protection Act.
12. This consent is issued as per the delegation of powers to HOD's vide Board Office Order No. 31/2013 dtd. 01/03/2013.

13. The Total capital investment is Rs 9.44Cr (existing CI Rs. 7.70 and proposed CI 82.0 Lakhs) as per C. A Certificate submitted by the industry.

Mirashe
26/05/14

(P. K. Mirashe)
Asst. Secretary (Technical)

To,
M/s. Orax Pharma Pvt. Ltd.,
Plot No. B-5, Phase-I, MIDC, Dombivali,
Dist. Thane

Copy to: 1) Regional Officer, MPCB, Kalyan & 2) Sub-Regional Officer, MPCB, Kalyan-I - They are directed to ensure the compliance of consent conditions.
3) Chief Accounts Officer, MPCB, Mumbai 4] Cess Branch, MPCB. 5] Master file.

Received Consent fee of -

Amount	D.D. No.	Date	Bank Name
5,100/-	094087	26.05.2014	HDFC Bank

Maharashtra Pollution Control Board